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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,220	11/15/2001	Alan John Kingsman	674523-2011	8450
20999	7590	11/17/2003	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,220

Applicant(s)

KINGSMAN ET AL.

Examiner

Stacy B Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-21 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 9, 10 and 16-21 is/are ~~allowed~~ free of the prior art of record. SBC 11/7/03
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed September 17, 2003 is acknowledged and entered. Claims 1-6 and 9-21 are pending. Claims 1-6, 9-10, 13 and 16-21 are pending and examined. Claims 11, 12, 14 and 15 are withdrawn from consideration being drawn to non-elected inventions.
2. The rejection of claims 1-10 and 13 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn in view of Applicant's persuasive arguments. The rejection of claims 1-10, 13, 16 and 18 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment. The rejection of claims 16 and 17 under 35 U.S.C. 102(b) as being anticipated by Combadiere *et al* (WO97/45543) is withdrawn in view of Applicant's persuasive arguments.
3. Upon further review and consideration of the elected claims, the following new rejection is applied. The Office regrets any inconvenience to Applicant.

Claim Rejections - 35 USC § 112

4. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a making an attenuated infectious retrovirus pharmaceutical composition, does not reasonably provide enablement for making an infectious non-attenuated retrovirus pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The breadth of the claim is unreasonable, encompassing a non-attenuated infectious retrovirus as a pharmaceutical. The nature of the invention is the production of high titers of an infectious retrovirus and uses thereof, such as a pharmaceutical composition which must have some therapeutic benefit *in vivo*. The state of the

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art and common knowledge tell one of skill in the art that a non-attenuated infectious retrovirus pharmaceutical has no apparent therapeutic benefit in vivo. The only function of such a product would be a potentially lethal infection of a subject with retrovirus. The level of predictability in the art is high with regard to the infectious and lethal activities of retroviruses in vivo. There is no guidance as to how to use a non-attenuated infectious retrovirus as a pharmaceutical. There are no working examples of such a use. Therefore, given the breadth of the claim, the state of the art, the lack of guidance and working examples, and the high level of predictability regarding retroviruses' ability to infect, the quantity of experimentation needed to use the invention would be undue and possibly non-existent. Therefore, the claim lacks enablement for its full scope.

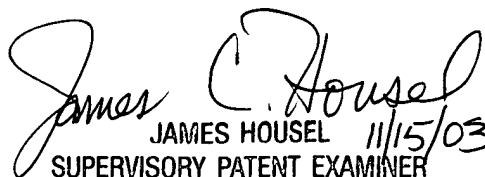
Conclusion

5. Claims 1-6, 9-10, 13 and 16-21 are free of the prior art.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy B. Chen
November 7, 2003


JAMES HOUSEL 11/15/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600